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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/784,121 | 02/16/2001 | Robert C. McIver | 81455-464 | 2558 |

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| EXAMINER | |
|---|---|
| SHEIKH, HUMERA N | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/784,121 | MCIVER ET AL. | |
| | Examiner | Art Unit | |
| | Humera N. Sheikh | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040520*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### Status of the Application

Receipt of the Response to Restriction/Election Requirement and the Applicant's Arguments/Remarks made in the amendment, both filed 01/30/04 is acknowledged.

In view of the state of the art, the Species Election requirement for Claim 16 has been *withdrawn*.

Claims 1-17 are pending. Claims 1-17 are rejected.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1-4, 8, 10, 11, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goto (EP 0 389 700 A1).**

Goto teaches a soft capsule and globular material prepared from (natural high-molecular) agar-agar as the base material that is applied to pharmaceuticals, chemicals, cosmetics, foodstuffs, miscellaneous goods and the like, wherein the soft capsule comprises sorbitol (carbohydrate), plasticizers, stabilizers, colorant, perfume, disintegrator assistant and corrigent (see reference page 3, lines 18-24 and Abstract).

The examples demonstrate various agar-agar containing capsule formulations.

Example 1, pgs. 3-4, Goto teaches a vegetable soft capsule containing medicine Vitamin E, soybean oil and agar-agar (25 mg) and glycerin and water as the capsule film.

In Example 6, pg. 6, a soft capsule for water-containing foodstuff is taught whereby the soft capsules each containing perfumes, seasonings and nutritive substances were prepared and the resultant capsules were admixed with custard pudding, yogurt, milk or the like.

Similarly, in Example 8 on pg. 6, Goto teaches a well-nourished soft capsule for medicated drink (medicine).

Regarding the claimed percentages or amounts, no criticality is seen in the claimed percentages/amounts, since it would have been obvious to one skilled in the art that suitable percentages or amounts can be determined through the use of routine or manipulative experimentation.

**Claims 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goto (EP 0 389 700 A1).**

Goto teaches a soft capsule and globular material prepared from (natural high-molecular) agar-agar as the base material that is applied to pharmaceuticals, chemicals, cosmetics, foodstuffs, miscellaneous goods and the like, wherein the soft capsule comprises sorbitol (carbohydrate), plasticizers, stabilizers, colorant, perfume, disintegrator assistant and corrigent (see reference page 3, lines 18-24 and Abstract).

In Example 5, pg. 5, Goto teaches a soft capsule for water-containing cosmetics wherein the soft capsule contains perfume, oil, nutritive substance, agar-agar, glycerin. The soft capsule was then mixed with water-containing cosmetics such as lotion, cream, milky lotion, *shampoo and the like.* Globular materials can be prepared with these ingredients and may then be mixed with massage cream to serve a scrub cosmetic.

Example 10 demonstrates a soft capsule for bath lotion, comprising agar-agar and perfumes.

**Claims 1-11, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnes *et al.* (WO 85/03414).**

Barnes *et al.* teach an extrudable encapsulation particulate matrix composition having improved loading capacity for oils, flavors, fragrances, agricultural chemicals, drugs, etc., whereby the matrix composition contains carbohydrates such as maltodextrin (starch hydrolysate), modified starches and agar-agar in an amount of

0.25-5% (instant claims require 1-7%). The maltodextrins have a dextrose equivalent being in the range of 3-40. (see reference pages 2-9).

According to Barnes *et al.*, the encapsulating matrix composition has an improved loading capacity of up to about 40%. A particulate composition comprising the foregoing matrix composition in combination with liquid or volatile active ingredients is also taught, whereby other ingredients include water, emulsifiers, and viscosity agents in effective quantities (generally below 10%) (pg. 5, lines 2-19).

The role of the maltodextrin is to provide matrix bulk, and an emulsion, prior to extrusion, of reasonable viscosity. Various modified starches can be used, such as 'Amaizo ARD 2326', which is an octenyl succinic anhydride derivative. Either of these components may be replaced in part with natural gums, i.e., gum acacia, gum arabic, corn syrup solids having a dextrose equivalent below about 40, or sucrose. Sucrose can also be replaced with equivalent amounts of glucose, sweeteners, cellulose compounds or polyhydric alcohols such as sorbitol, mannitol or the like (pg. 5, line 23 – pg. 6, line 16).

Flavor systems containing high levels of water (fruit essences) can be encapsulated according to the teachings of Barnes *et al.* The composition may contain about 20% maltodextrin, about 30% Capsul, and about 40% flavor, of which 20% is oil and 80% is carrier. Various flavoring agents may be employed, for example orange oil, lemon oil, grapefruit oil, fruit essence extracts, etc. Mixtures of flavoring agents may also be used. It is preferred to add an edible oil and/or an edible emulsifying agent to the purified fruit essence so that it will emulsify properly with the matrix (pg. 7-pg. 8, line

19). The proportion of the flavoring agent to be incorporated in the carrier base may be varied depending on the flavor strength desired in the final product. Active agents include organoleptics i.e., flavors or fragrances, agricultural chemicals, flavor enhancers, pharmaceuticals, etc. These encapsulating matrices materials are soluble in water to release the active ingredient. They may be used as ingredients of candy or lozenges or breath deodorants (pg. 8, line 27- pg. 9, line 4).

**Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sair *et al.* (US Pat. No. 4,232,047).**

Sair et al. teach a food supplement concentrate of an ingestible agent such as a seasoning, flavoring, essential oil, vitamin, mineral and mixtures thereof encapsulated, enveloped or encased as a dispersed microphase within a matrix of an encapsulating medium such as a starch, protein, flour, modified starch, gum and mixtures thereof. The concentrate is prepared by mixing the edible agent and the encapsulating medium with a limited quantity of water adequate to permit conversion of the mixture, under applied *extrusion* pressure and controlled heat, to provide a dense glassy extrudate with ingestible agent dispersed therethrough in microform (see Abstract).

The method of Sair et al. has been found particularly useful in the encasement of essential oils or artificial flavors, whereby the extruded product can be ground or otherwise reduced to any desired particle size (column 4, lines 31-33; col. 5, lines 18-27). The examples demonstrate stabilized extruded products whereby extrusion, drying and grinding were conducted.

**Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

*hns* H.N.S.

May 20, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600